

**Summary of Safety and Effectiveness  
Smith & Nephew Richards Inc.  
Ultium Spinal Plating System**

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**Substantial Equivalence Information**

The Ultium Spinal Plating System is similar to the following systems:

1. Simmons Plating System - Smith & Nephew Orthopaedics
2. Rogozinski Spinal Rod System - Smith & Nephew Orthopaedics
3. Steffee Plating System (VSP) - Acromed
4. DynaLok System - Danek

K962784

All of the devices listed above are similar in design to the Ultium Spinal Plating System. The safety and effectiveness of the Ultium Spinal Plating System is based on the long history of use of these devices in the market place.

**Device Description**

The Ultium Spinal Plating System includes plates, washers, a locking nut, standard bolts, and offset bolts. All components are manufactured from a titanium alloy.

**Indications for Use**

**Posterior Fixation / Attachment (Pedicule fixation):** The Ultium Spinal Plating System bolts when placed in the pedicles are intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. When used as a pedicle screw system, the bolts may be used for the indications specified previously to affix the plates to vertebral levels L3 to S1 inclusive.

**Anterior Fixation / Attachment (anterolateral intervertebral bodies).** The Ultium Spinal Plating System when attached anterolaterally to the vertebral bodies of levels T10 to S1, inclusive, is intended for the treatment of: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disk confirmed by historical and radiographic studies); pseudarthrosis, stenosis, scoliosis, spondylolisthesis; unsuccessful previous attempts at spinal fusion; or tumor resection.

**Mechanical Testing**

Mechanical testing was performed according to ASTM standard test methods. All of the test results indicate that the Ultium Spinal Plating System is capable of withstanding *in vivo* loading without failure.